|  |  |
| --- | --- |
| **TGHN-256x151px****Standard Operating Procedure** | **SOP No:** **Version: 1****Effective Date:**  |
| **Title: Identifying Critical Suppliers** |
|  | NAME | **SIGNATURE** | **DATE** |
| **PREPARED BY** |  |  |  |
| **REVIEWED BY** |  |  |  |
| **QA UNIT****AUTHORITY** |  |  |  |
| **APPROVAL****AUTHORITY** |  |  |  |

1. **Purpose/scope**

To describe the procedure for how critical service providers (suppliers/vendors) are identified, selected and managed to ensure they are suitably qualified, skilled, experienced or otherwise able to provide the quality of service required for a clinical trial conducted by [institution]. This SOP covers service providers such as laboratories, caterers, consultants (e.g. specialists, quality assurance or regulatory professionals, data management companies etc.) but does not cover the acquisition or manufacturing of medicines (investigational medicinal product, comparator, rescue medicines etc.) or acquisition of equipment and consumables.

1. **Templates/forms**

AD09.1 Confidential disclosure agreement (internal suppliers)

1. **Glossary/definitions**

None

1. **Responsibilities and procedure**

**Identification and selection of supplier/vendor**

* 1. The Principal Investigator (PI) should ensure all suppliers/vendors who provide a critical service for a particular clinical trial are adequately qualified, experienced, skilled and/or otherwise able to comply with the required level of quality.
	2. The depth of investigation into suitability of the supplier/vendor will depend on the type of service required and the sponsor's requirements. Any or all of the following criteria may be used:
* Previous positive experience (including a positive audit report)
* Recommendation from another site/CRO/Sponsor
* Enquiry into the supplier's scope of work, experience, certification and/or accreditation. This will depend on the type of service.
* Pre-qualification audit by an appropriately qualified member of the [group] or an external company/consultant. An audit will typically include assessing compliance against applicable guidelines and/or regulations (e.g. Good Clinical Laboratory Practice, their own SOPs) including review of relevant documentation (e.g. accreditation certificates, CVs). NB outstanding actions relating to findings must be completed before contracts are signed.
* Review of available disqualification lists (e.g. FDA).
	1. A suitably qualified member(s) of the [group] team will be tasked with coordinating the development of a list of protocol-required activities/deliverables and questions regarding the potential supplier/vendor's scope of work, experience, certification and/or accreditation according to applicable regulatory requirements.
		+ 1. For a laboratory, this will include practical considerations such as location, test time logistics, availability of tests (and acceptability of reference ranges), accreditation with SANAS (or alternative quality assurance provisions), sample collection and shipment logistics, reporting (including electronic uploads if relevant) and financial aspects in relation to the available budget.
			2. For a catering company this will include practical considerations such as location, availability of required menu (and ability to adhere to protocol requirements), delivery and collection logistics, supply of catering equipment and staff as required. In addition, applicable certification (e.g. as regards food quality, Halaal) and financial aspects in relation to the available budget.
	2. The site must not send any information about the trial to the potential supplier/vendor until a confidentiality disclosure agreement (CDA), or equivalent, is signed by both parties. However, anonymised information may be sent prior to such an agreement with the sponsor's permission. External service providers/vendors may provide their own mutual CDA for submission to the UCT Contracts Office or the Contracts Office may provide a generic template for review/comment by the potential supplier/vendor. Internal suppliers/vendors (e.g. specialists) may use the template [group] CDA (AD09.1).

**Contracts**

* 1. The decision to engage the services of a supplier/vendor will be made based on the information gathered above, the quote for the work and practical considerations (e.g. location of laboratory, sample collection logistics, ease of reporting etc.).
	2. A member of the site team will liaise with the UCT Contracts Office when engaging the services of external companies/personnel. Arrangements with internal personnel and/or departments, however, may be directly with the Principal Investigator (PI, or designee).
	3. In both cases there should be a clear written agreement between the parties as to issues such as the scope of the service/tasks, division or delegation of responsibilities, timelines for delivery, applicable standards, reporting and retention of records (or samples if relevant), payment terms, and indemnity/insurance issues.
	4. A copy of the signed contract and any subsequent amendments will be filed in the Investigator Site File.

**Oversight/management**

* 1. A member of the site team with appropriate qualification and/or experience is assigned responsibility to monitor the services provided by the contracted party and report as necessary to the PI any deviations from the agreement. Such issues will be raised with the service provider/vendor at the earliest opportunity and appropriate steps taken to assure compliance. Full documentation is required for the trial records.
	2. Deviations will also be reported to other appropriate parties according to their requirements (e.g. sponsor, ethics committee and/or Medicines Control Council).
	3. Serious breaches may require termination of the contract and/or a claim for financial compensation. The latter will be discussed with the UCT Contracts Office before any action is taken.
	4. Payments are facilitated according to the contract through the relevant Finance Office.
1. **Document history:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Version No.** | **Date** | **Reviewer** | **Details of changes** |
| 1 | add | NA | NA - first version of SOP |